Application No.: 0 24,841 Amendment dated April 3, 2003 Reply to Office Action of January 8, 2003

## **REMARKS/ARGUMENTS**

Claims 20-30 remain in this application. Claims 34-41 are newly added. Claims 6-19 have been canceled. Claims 1-5 and 31-33 have been withdrawn.

The Examiner has acknowledged that claims 20-30 are allowable if the pending rejections are overcome; no prior art rejections were made. Claims 1-5 and 31-33 have been withdrawn as a result of an earlier restriction requirement. New claim 34 recites that the nucleic acid is a DNA, RNA, or nucleic acid analogues (support in the specification: page 26, lines 25-29). New claims 35-41 are drawn to oligonucleotides capable of hybridizing to nucleic acids comprising SEQ ID NO: 1 or the complement thereof, or SEQ ID NO: 4 or the complement thereof (support in the specification: page 26, lines 21-29). Support for new claims 35-41 can be found in the Specification including the cited references.

The Examiner objects to the Title as it is not descriptive. Applicants will amend to correct the Title as appropriate upon allowance.

The Examiner rejects claims 20-30 under 35 U.S.C. 112, first paragraph, alleging that the specification does not enable a nucleic acid consisting "essentially of" at least 12 contiguous nucleotides from SEQ ID NO: 1 or SEQ ID NO: 4 as recited in claim 20. Claims 20-25 have been amended to be free of the objected language. Thus the objection and the corresponding rejection are moot in view of this amendment. This rejection thus should be withdrawn.

The Examiner rejects claims 20-30 under 35 U.S.C. 112, second paragraph, alleging that they are indefinite for failing to particularly point out and distinctly claim the subject matter because of the limitation, "consisting essentially of." Claims 20-25 have been amended to be free of the objected language.

The Examiner also rejects under same because the limitation, "about 75 [nucleotides]", is vague and indefinite. The Examiner alleges that because the invention when defined "in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table" using the term "about" is "unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision." In response to the rejection based on this line of argument, Applicants respectfully point out to the Examiner that the language "about" which is used to recite the number of nucleotides, in particular in the biotechnology arts, is nothing new and has been well accepted by the USPTO. As an example, the following patents have been issued by at least four different examiners that took place in 1998 and 2003 in which the instantly objected language ("about") was recited:

## 5,770,370 issued June 23, 1998

- 1. A nuclease protection assay comprising:
- (A) attaching a nucleic acid probe comprising a first nucleotide sequence to a solid surface area;
- (B) contacting the nucleic acid probe with a nucleic acid template under conditions that

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promote hybridization between complementary polynucleotides, forming a probe-template complex if the template includes a segment that is complementary to the probe; (C) contacting the probe-template complex with a nuclease effective to selectively cleave the nucleotide bonds of (1) the first nucleotide sequence when the first nucleotide sequence is single stranded or (2) mismatched regions of the first nucleotide sequence when the first nucleotide sequence is in duplex nucleic acid; and (D) detecting the presence of duplex nucleic acids formed by the probe and template nucleic acids by detecting the presence of the first nucleotide sequence.

16. The assay of claim 1 used for the identification or quantitation of an expressed mRNA, wherein the nucleic acid probe comprises at its 3' end a polyT segment and the first polynucleotide sequence comprises at least **about** 10 **nucleotides** distinct from the polyT segment, wherein the polyT-containing nucleic acid probe is complementary to the mRNA.

## 6,509,149 issued January 21, 2003

- 1. A synthetic, modified oligonucleotide fully complementary, throughout its entire length, to a portion of a human papillomavirus E1 open reading frame contained within (a) nucleotide -17 to nucleotide +29, and including at least 21 nucleotides, (b) nucleotide -17 to nucleotide +19, and including at least 15 nucleotides, or (c) nucleotide +2 to nucleotide +29, and including at least 15 nucleotides.
- 16. The oligonucleotide of claim 1 comprising at most **about** 30 **nucleotides** and comprising a sequence selected from the group consisting of SEQ ID NOS: 2, 3, 4, 5, 6, 7, 8, 9, 10.

## 6,514,736 issued February 4, 2003

- 1. A kit for the amplification of a nucleic acid, said kit comprising:
- (a) first and second oligonucleotide primers, said oligonucleotide primers differing in sequence from each other;
- (b) an oligonucleotide probe that differs in sequence from said first and second oligonucleotide primers; and
- (c) a DNA polymerase enzyme; wherein at least one primer contains at least one nucleotide which is not complementary to the specific sequence to be amplified.
- 5. The kit according to claim 1 in which said two oligonucleotide primers each contain **about** 15 to 25 **nucleotides**.

The use of the language "about" to recite the length of a nucleic acid thus is well established and accepted by the USPTO. Nevertheless, whether the Examiner agrees with this USPTO practice or not, Applicants respectfully submit that the "about" language as used to recite the instant claims does not render them vague and indefinite. According to MPEP 2173.02, definiteness of claim language must be analyzed, not in vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim

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interpretation that would be given by one possessing the ordinary skill in the pertinent art at the time of the invention. The content of the instant application includes nucleic acid fragments of at least 12 contiguous nucleotides in length. The Examiner did not cite any prior art, let alone any prior art that is close to the invention, that would necessitate a distinction of the claims from the cited prior art. Applicants therefore submit that the claims, when taken as a whole, are definite and that one skilled in the art would understand what's being claimed from the limitation of about 75 nucleotides.

With respect to the rejection of Claim 20 under same because, as the Examiner alleges, it is unclear as to what is included in the claim as recited. Applicants thank the Examiner for her suggestion of amending the claim to overcome this rejection. However, Applicants respectfully submit that the claim as currently recited is not vague or indefinite. Claim 20 clearly recites that the nucleic acid is of at least 12 nucleotides in length derived from SEQ ID NO: 1 or its complementary sequence, SEQ ID NO: 4 or its complementary sequence.

In view of the foregoing discussion with respect to the 35 U.S.C. 112, second paragraph rejection, Applicants submit that the rejection should be withdrawn.

Applicants respectfully request that a timely Notice of Allowance be issued for this case.

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